

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Bruce Rosenzweig, M.D.)

Pending in *In re C. R. Bard, Inc. 2:10-md-2187*, MDL 2187, is C. R. Bard, Inc. (“Bard”)’s *Daubert* motion¹ to Exclude or Limit Certain Opinions and Testimony of Bruce Rosenzweig, M.D. [ECF No. 4576]. The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard’s motion is **GRANTED in part, DENIED in part, and RESERVED in part.**

I. Background

These groups of cases reside in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation (“MDL”) concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 29,000 cases currently pending, approximately 3,000 of which are in the C. R. Bard, Inc. MDL, MDL No. 2187.

¹ Rather than refile, Bard entered a “notice” adopting prior *Daubert* motions that incorporate the parties positions previously formulated in Waves 1 and 2.

In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 236, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:10-md-02187, Jan. 27, 2017, <https://www.wvsc.uscourts.gov/MDL/2187/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general experts in the main MDL, MDL 2187, and to identify which cases the motion would affect.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with

evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct” – “[a]s with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the

relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Rosenzweig is an urogynecologist and professor of obstetrics and gynecology in Chicago, Illinois. He offers several different opinions, a number of which Bard contends is improper: (1) opinions regarding Bard’s knowledge, state of

mind, or corporate conduct; (2) narrative descriptions of Bard documents; (3) legal opinions; (4) opinions regarding the insufficiency of Bard's testing; (5) opinions regarding the alleged inadequacy of the Bard Patient Brochures; and (6) specific causation opinions based on general inferences from his background and experience.

For the reasons discussed below, Bard's motion is **GRANTED in part, DENIED in part, DENIED as moot in part, and RESERVED in part.**

1. Opinions Regarding Bard's Knowledge, State Of Mind, or Corporate Conduct

Bard complains that Dr. Rosenzweig's opinions are riddled with improper testimony regarding Bard's corporate knowledge and state of mind. *See, e.g.*, Notice of Adoption of Mot. to Exclude or Limit Certain Ops. & Test. of Dr. Bruce A. Rosenzweig, M.D. in Wave 4 & Wave 5 Cases, Ex. C at 6 ("Despite [Bard's] knowledge about the problems related to heavy weight, small pore mesh like the Align mesh and the problems it causes in pelvic tissues and patients, Bard has done nothing to change the mesh and continues to promote and sell the product with the same, heavy weight small pore mesh..") [ECF No. 4576-3]; *Id.* Ex. A (Rosenzweig's Report) at 36 ("Bard was or should have been aware that shrinkage of its Align mesh not only could, but would, occur and that this shrinkage could lead to painful complications in women implanted with Align, such as multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain" etc.) [ECF No. 4576-2]. As I have previously discussed, these opinions do not assist the jury. Accordingly, they are **EXCLUDED**.

2. Narrative Descriptions of Bard Documents

Bard argues that much of Dr. Rosenzweig's expert report is a summary of company documents. Bard, for instance, identifies three instances wherein Dr. Rosenzweig provides a narrative of corporate documents in support of his opinions regarding Bard's knowledge, state of mind, or corporate conduct. As I previously determined, Dr. Rosenzweig's opinions on these matters are excluded, as they do not assist the jury. As such, narrations of the same are **EXCLUDED**.

3. Legal Opinions

Bard seeks to exclude certain opinions expressed by Dr. Rosenzweig that amount to legal conclusions. For instance, Bard notes, Dr. Rosenzweig's expert report states, "Bard failed to act as a reasonable and prudent medical device manufacturer." *See, e.g.*, Notice of Adoption of Mot. to Exclude or Limit Certain Ops. & Test. of Dr. Bruce A. Rosenzweig, M.D. in Wave 4 & Wave 5 Cases, Ex. C at 10; *Id.* (stating that Bard "deviated from the standard of care required of a reasonable medical device manufacturer by failing to adequately disclose these known adverse reactions and risks to physicians"). These statements draw legal conclusions from the facts. In the Fourth Circuit, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Whether Bard failed to act as a reasonable and prudent medical device manufacturer is a question for the jury. To be clear, Dr. Rosenzweig may offer opinions that, as a physician, he does not believe the mesh in question is suitable for treatment, but his opinions cannot be phrased as legal conclusions. Therefore, these statements are **EXCLUDED**.

4. Opinions Regarding the Purported Insufficiency of Bard's Testing

Dr. Rosenzweig opines that Bard “should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene used in Align to alter inside the woman’s body (as well as other complications), and if so, what materials are released into the body as a result, and what impact would those materials have on the body.” Notice of Adoption of Mot. to Exclude or Limit Certain Ops. & Test. of Dr. Bruce A. Rosenzweig, M.D. in Wave 4 & Wave 5 Cases, Ex. C at 12 (citing Rosenzweig Report at 16) [ECF No. 4576-2]. As a medical professional, Dr. Rosenzweig reported reviewing information from clinical trials regularly, experience reviewing clinical trials for peer reviewed scientific journals related to gynecology and urogynecology, as well as personal participation in clinical trials. Based on his experiences, Dr. Rosenzweig is qualified to opine on the need for clinical trials.

Furthermore, Dr. Rosenzweig explains in detail the basis for his opinion that Bard’s training was inadequate, including references to medical literature and internal documents. Therefore, Bard’s motion on this point is **DENIED**.

5. Opinions Regarding the Alleged Inadequacy Of The Bard Patient Brochures

Dr. Rosenzweig opines that the patient brochures issued by Bard were inadequate, misleading, and failed to inform patients about particular risks of the mesh products. Rosenzweig Report at 62.

Bard first argues generally that Dr. Rosenzweig is not qualified to testify about the adequacy or inadequacy of a patient brochure. As I previously held,

Dr. Rosenzweig's testimony reveals that he has consulted on product warnings in the past and qualified to testify generally on the adequacy of product warnings and marketing materials.² The parties have not presented any evidence in the interim that suggests that my previous holding is mistaken or no longer applicable here. I therefore **FIND** that Dr. Rosenzweig is qualified to testify generally on the adequacy of the patient brochures produced by Bard.

Bard also asserts that Dr. Rosenzweig provides no reliable basis for his conclusion that the warnings contained in the Bard Patient Brochures were inadequate. The plaintiffs, however, make no effort to identify support for Dr. Rosenzweig's conclusions in his report or deposition testimony. At this point, I am unable to determine the full scope of Dr. Rosenzweig's opinions and their foundation. Therefore, I **RESERVE** for trial my ruling on Dr. Rosenzweig's opinions regarding the alleged inadequacy of the bard patient brochures.

1. Specific Causation Opinions Based on General Inferences from His Background and Experience

According to Bard, Dr. Rosenzweig testified at his deposition that many plaintiffs he examined suffered injuries attributable to "subclinical infection" caused by Bard's mesh. Notice of Adoption of Mot. to Exclude or Limit Certain Ops. & Test. of Dr. Bruce A. Rosenzweig, M.D. in Wave 4 & Wave 5 Cases, Ex. C at 16. Bard contends that from this general observation, others realized from scientific literature, and his practice, Dr. Rosenzweig inferred specific causation opinions concerning

² *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D. W. Va. 2014) (citing Rosenzweig Report at 55).

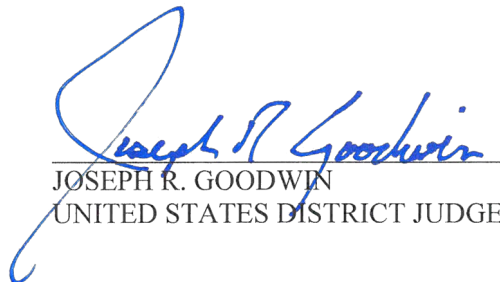
specific plaintiffs. As I stated previously, the motion currently before the court considers the parties' dispute pertaining to specific causation issues concerning other multidistrict litigation plaintiffs. It is therefore inapplicable to Bard Wave 4 cases and the motion on this point is **DENIED as moot**.

IV. Conclusion

To summarize, I **GRANT in part, DENY in part, DENY as moot in part, and RESERVE in part** Bard's motion concerning Dr. Bruce Rosenzweig, M.D. [ECF No. 4576] consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 23, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Barker, Lorie	2:13-cv-33690	4
Bivens, Geraldine L	2:16-cv-11116	4
Black, Brenda L	2:14-cv-00952	4
Branscome, Christine E	2:16-cv-10995	4
Brewer, Pamela R	2:16-cv-11135	4
Brown, Cathy	2:16-cv-10807	4
Carnahan, Kathy	2:13-cv-24208	4
Cooley, Dedra	2:14-cv-07543	4
Cuffee, Carolyn D	2:14-cv-02528	4
Degarmo, Nora	2:12-cv-07578	4
Drake, Theresa	2:16-cv-03709	4
Edwards, Claudine	2:14-cv-27463	4
Ford, Janet Marie	2:14-cv-09878	4
Gardiner, Gloria	2:13-cv-15209	4
Gilbert, April D	2:16-cv-11118	4
Gritten, Linda	2:16-cv-03707	4
Guerrero, Angelia	2:14-cv-14209	4
Hall, Cardisa M	2:16-cv-11113	4
Henderson, Teresa	2:16-cv-03779	4
Holmes, Robin	2:13-cv-01524	4
Hummel, Niki	2:13-cv-32359	4
Johnson, Nancy	2:13-cv-19736	4
Jones, Thelma J	2:16-cv-03719	4
Keisling, Linda	2:16-cv-03721	4
Lackey, Danielle R	2:16-cv-11011	4
Landers, Samantha	2:13-cv-26574	4
Ledwein, Judy	2:16-cv-03778	4
Lee, Frankie	2:12-cv-07570	4
Long, Pamela D	2:13-cv-20881	4
Martin, Judy A	2:16-cv-11103	4
Massey, Shannon L.	2:14-cv-01027	4
McWilliams, Brenda K	2:16-cv-11104	4
Miller, Alice F	2:16-cv-11014	4
Moore, Carol	2:16-cv-03842	4
Moore, Carolyn S	2:14-cv-00606	4
Morgan, Khristina S	2:16-cv-11016	4
Nadeau, Susan J	2:16-cv-11112	4
Nall, Stephanie	2:13-cv-01526	4
Newell, Carmen	2:13-cv-16405	4
Phelps, Inna V	2:16-cv-11114	4
Pickering, Hope	2:16-cv-03896	4
Politi-Topal, Kathleen D.	2:14-cv-01411	4
Powell, Mary C	2:16-cv-11017	4

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Powers, Lisa R	2:16-cv-11041	4
Priddy, Judy M	2:13-cv-10318	4
Purcell, Kim	2:13-cv-34058	4
Radatz, Mary L.	2:13-cv-17989	4
Raines, Cynthia Ann	2:13-cv-26748	4
Richardson, Cynthia O	2:13-cv-20036	4
Richardson, Demetria	2:12-cv-02564	4
Rodericks, Rhonda K	2:16-cv-11115	4
Rogers, Rosemary J	2:16-cv-11106	4
Sheaffer, Julie A	2:14-cv-05601	4
Silvia, Diane	2:14-cv-25366	4
Smith, Tamela	2:13-cv-30640	4
Speetzen, Michelle	2:13-cv-12416	4
Stapel, Catherine	2:14-cv-25362	4
Stewart, Mary Sue	2:14-cv-27466	4
Stoddard, Sloane	2:14-cv-11940	4
Struble, Maureen	2:16-cv-03817	4
Swiney, Ernestine F	2:16-cv-11021	4
Teeples, Mistie D	2:16-cv-11020	4
Toulson, Patricia	2:16-cv-03816	4
Urdike, Melody A	2:16-cv-11035	4
Weber, Erika	2:16-cv-11105	4
Wilson, Elizabeth J	2:14-cv-14119	4
Woodard, Elizabeth E	2:16-cv-11040	4
Alvey, Christine	2:16-cv-07705	5
Bailey, Carla	2:16-cv-06362	5
Barton, Joan	2:16-cv-07655	5
Bess, Joyce	2:16-cv-06318	5
Clarke, Janice	2:16-cv-10809	5
Cole, Jeanene	2:16-cv-07402	5
Collins, Dana	2:16-cv-06739	5
Corley-Davis, Celia	2:16-cv-10811	5
Crook, Julie	2:16-cv-06360	5
Crowe, Karen F	2:16-cv-11136	5
Currie, Arlene	2:16-cv-10814	5
Daily, Catherine T	2:16-cv-11137	5
Davis, Debra M	2:16-cv-11139	5
Dennis, Barbet	2:16-cv-10815	5
Donley, Teresa	2:16-cv-07322	5
Donovan, Thoris L	2:16-cv-11142	5
Duncan, Andrea	2:16-cv-10816	5
Ellis, Karen	2:16-cv-07694	5
Elrod, Josephine	2:16-cv-04032	5

PLAINTIFF	CURRENT CIVIL ACTION #	WAVE
Fay, Paula A	2:16-cv-11144	5
Frederick, Cheryl D	2:16-cv-11266	5
Hale-Cuellar, Patricia A	2:16-cv-11150	5
Hauber, Elizabeth A	2:16-cv-11158	5
Herrera, Wynde Lynn	2:16-cv-10819	5
Hill, Mignon M	2:16-cv-11161	5
Jasso, Mary	2:16-cv-06361	5
Jeffries, Lynda	2:16-cv-11798	5
Johnson, Elisa J	2:16-cv-11147	5
Josey, Tammy	2:16-cv-11803	5
Knernschiold, Peggy	2:16-cv-06743	5
Kolodzyk, Virginia L	2:16-cv-11163	5
Krishnan, Meera	2:16-cv-06740	5
Kyes, Marilyn	2:16-cv-11804	5
Leyba, Lorraine	2:13-cv-16401	5
Lingenfelter, Nancy	2:16-cv-07610	5
Mahnke, Joyce C	2:16-cv-11167	5
Martinez, Tammy	2:16-cv-10821	5
Mathis, Nellie	2:16-cv-08014	5
Miecznikowski, Jennifer C	2:16-cv-11169	5
Morrill, June	2:16-cv-11170	5
Nichols, Brandey R	2:16-cv-11186	5
Piper, Connie	2:16-cv-11811	5
Prince, Marjorie	2:16-cv-04949	5
Reynolds, Cassandra	2:16-cv-11175	5
Roberts, Carla	2:16-cv-06741	5
Roberts, Sheila	2:16-cv-05003	5
Smith, Sandra	2:16-cv-11817	5
Stephenson, Erin	2:16-cv-11819	5
Stevens, Terri L	2:16-cv-11820	5
Tatum, Tuesday	2:16-cv-11821	5
Thompson, Reba	2:16-cv-04536	5
Watson, Charlotte	2:16-cv-03989	5
Yoder-Brady, Bobbye	2:16-cv-03954	5
Young, Carolyn	2:16-cv-04037	5